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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,840	10/30/2003	David W. Wynn	MCP-5021	9284

27777 7590 02/05/2010

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EXAMINER	
BROWN, COURTNEY A	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
02/05/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/697,840	WYNN ET AL.	
	Examiner	Art Unit	
	COURTNEY BROWN	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-6,9-15,17-21 and 24-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-6,9-15,17-21 and 24-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed November 4, 2009. Claims 1, 3-6, 9-15, 17-21 and 24-34 are pending in the application. Claims 1 and 20 have been amended. Claims 2,7,8,16, 22 and 23 have been cancelled. Claims 31-34 are newly added. Claims **1, 3-6, 9-15, 17-21 and 24-34** are being examined for patentability.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

The obviousness-type double patenting rejection of claims 1, 4, and 9-12 over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967). **is maintained.**

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4 and 9-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by co-pending application10/697,546.

Copending claims 13-15, 19 and 26 and instant claims 1,4 and 9-12 teach the same liquid suspension dosage form comprising: a.) particles of an NSAID and/or acetaminophen substantially covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming

polymer and an enteric polymer and the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1 and b.) a vehicle for the administration of the particles comprising water or mixtures of water and a pharmaceutically acceptable water-miscible co solvent selected from the group consisting of glycols, alcohols, and glycerol. The difference between the invention of the instant application and that of copending Application No. 10/697,546 is that the instant application claims a liquid suspension comprising only a controlled release composition as opposed to a liquid suspension comprising a controlled release composition and an immediate release composition. Clemente et al. teach that an extended release formulation can be extremely beneficial at night, so that a child can rest or sleep comfortably for a sufficiently long period of time while under the effects of the analgesic (acetaminophen) if the child is in pain, or under the effects of the antipyretic if the child is febrile(column 20, lines 25-36). One would have been motivated to make this combination in order to receive the expected benefit of having pharmaceutically acceptable liquid suspension system that has a therapeutic effect over an extended period of time without exposing the patient such as a child to a large amount of active compound. From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is produced in copending application 10/697,546.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's arguments filed on November 4, 2009, with respect to the rejection of claims 1, 4 and 9-12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-15, 19, and 26 of copending Application No. 10/697,546 in view of Clemente et al (US Patent 6,126,967) have been fully considered but they are not persuasive. Applicant states that the '546 Application is still pending in the U.S. Patent Office and has not issued as a patent. Additionally, Applicant expects that the instant provisional double patenting rejection will be the only rejection remaining following consideration of this amendment. Thus, As set forth in MPEP §804(a), Applicant requests that the examiner withdraw the nonstatutory obviousness-type double patenting and permit the application to issue as a patent . However, the nonstatutory obviousness-type double patenting rejection is not the only rejection remaining has been maintained until a terminal disclaimer is filed.

New Rejection(s) Necessitated by the Amendment filed on November 4, 2009

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 33 depend of claim 29. However, claim 33 is directed to a composition and claim 29 is directed to a method which is a different statutory class of invention. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 9-15, 17-21, and 24-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shah et al. (US Patent 6,126,969, cited in the Office Action filed January 12, 2009) in combination with Singh et al. (US Patent 5,759,579,cited in the Office Action filed January 12, 2009) in view of Sakamoto et al. (US Patent 4,828,840), as evidenced by *Jinno Laboratory, School of Materials Science (http://chrom.tutms.tut.ac.jp/JINNO/DRUGDATA/01acetaminophen.html, March 1, 1996).*

Applicant's Invention

Applicant claims a pharmaceutical liquid suspension dosage form comprising: a). particles of an NSAID and/or acetaminophen, wherein 99% of said particles are covered with one layer of a controlled release composition wherein said controlled release composition comprises an insoluble film forming polymer and an enteric polymer, wherein the weight ratio of the insoluble film forming polymer and the enteric polymer is from about 80:20 to about 99:1; and wherein the average diameter of said particle is from about 20 to about 400 microns, and

b). a vehicle for the administration of the particles comprising water, wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least 8 hours after its initial administration to a mammal.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Shah et al. teach a dosage form comprising an extended releasing portion (abstract). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col. 5, lines15-20; examples). The coating comprises a combination of multiple polymers types and copolymers including film-forming polymers (col. 4, lines 40-58). The active agents include various well-known drugs including acetaminophen (tables 1 and 2). Shah et al. teach that the formulation can be dispersed in water in order to form a suspension (col. 4, lines 15-17). In the first embodiment, Shah et al. teach a formulation comprising only a sustained release

formulation (column 2, lines 58-end bridging to column 3 and column 4, lines 1-29). Thus, according to this particular embodiment of Shah et al., at least 99% of the actives are covered with one layer of a controlled release composition. Shah et al. teach a sustained-release acetaminophen formulation wherein acetaminophen is preferably provided in a finally divided form such as small particles or granules. The acetaminophen particles preferably have an average particle size between about 180 microns to 425 microns (column 2, lines 58-67).

Singh et al. teach a pharmaceutically acceptable liquid suspension system provided for solid finely divided pharmaceutical actives such as antihistamines, decongestants, antitussives, expectorants, non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen and phenacetin(column 2, lines 30-43), ibuprofen, naproxen, and ketoprofen (column 3, lines 12-15). The suspension system comprises water, xanthan gum and hydroxypropyl methylcellulose (abstract). Singh teaches the use of excipients known to the art including humectants such as glycerin and propylene glycol, preservatives such as sodium benzoate and paraben, sweeteners such as sodium saccharin, corn syrup and sorbitol solutions, menthol and various flavoring and coloring agents (column 4,lines 5-9). Singh teaches various examples of liquid suspension systems in columns 4-7 wherein the concentrations of the drug is about 3.2 % and the water content is at least 40%. Singh teaches that the liquid excipient suspending systems and the pharmaceutical compositions made therefrom should have an acidic pH of about 4-6.0 since

slightly acidic materials are easier to preserve and are more stable (column 2, lines 27-30).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the invention of the instant application and that of Shah et al. and Singh et al. is that the instant invention claims the use of particles of NSAID and/ or acetaminophen wherein said particles are covered with a controlled released composition comprising one layer of an insoluble film forming polymer and an enteric polymer in a weight ratio of about 80:20 to about 99:1 wherein the pharmaceutical liquid suspension dosage form has a duration of therapeutic effect for at least 12 hours. This deficiency in Shah et al. and Singh et al. is cured by the teaching of Sakamoto et al. Sakamoto et al. teach a controlled release formulation comprising a coated dosage form wherein the coating comprises a combination of water-insoluble polymers and enteric polymers (abstract). The formulation can last for longer than 10 hours) (col. 2, lines 30-35) and can comprise a wide range of active agents. The film coating comprises water-insoluble polymers such as cellulose acetate, ethyl cellulose and copolymers of polymethacrylate and trimethylammoniummethyl chloride methacrylate sold as Eudragit RS (col. 4, lines 5-15). The enteric polymers include hydroxypropylmethylcellulose phthalate, hydroxypropylmethylcellulose succinate acetate and copolymers of methacrylic acid and polymethyl methacrylate (col. 4, lines

16-25). The water-insoluble polymers are combined together (see column 2, lines 62-end bridging to column 3, lines 1-7) with the enteric polymers to form an extended release coating where the insoluble polymer is present in a ratio to the enteric polymer of 8.7:1 (see example 13) which is within the limits of the instant claims.

The difference between the invention of the instant application and that of Shah et al. and Singh et al. is that the instant invention claims a method for treating pain in a mammal in need thereof using a dosage form comprising particles of NSAID and/or acetaminophen and a liquid suspension pharmaceutical dosage form wherein the pKa of said NSAID is greater than the pH of said liquid suspension pharmaceutical dosage form.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the teachings of the cited references to arrive at a pharmaceutical liquid suspension dosage form comprising particles of an NSAID and/or acetaminophen being substantially covered with one layer of a controlled release composition. Shah et al. teach an orally administrable sustained-release dosage form and suggests that said sustained-release dosage form can be dispersed into water in the form of suspension (column 4, lines 14-17 of Shah et al.). It would have been obvious to modify the ratio of polymers in the extended coating of Shah et al. as taught by Sakamoto et al. in order to deliver a stable drug release over an extended period of

time, at least 12 hours. It would have been obvious to combine the teachings of Singh et al. , Shah et al., and Sakamoto et al. with an expected result of a stable controlled release formulation in the form of a suspension.

With regards to newly added claims 31-34, adding the limitation " a method for treating pain in a mammal in need thereof using a dosage form comprising particles of NSAID and/or acetaminophen and a liquid suspension pharmaceutical dosage form wherein the pKa of said NSAID is greater than the pH of said liquid suspension pharmaceutical dosage form", Singh teaches that the liquid excipient suspending systems and the pharmaceutical compositions made therefrom should have an acidic pH of about 4-6.0(column 2, lines 27-30). It is known in the art that the pKa of acetaminophen is about 9.7 (see Jinno Laboratory, School of Materials Science document). Thus, acetominophen has a pKa which is greater than the pH of the liquid suspension. Further, the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments, filed November 4, 2008, with respect to the 103 rejection of claims 1, 3-6, 9-15, 17-21, and 24-30 over Shah et al. (US Patent 6,126,969, in combination with Singh et al. (US Patent 5,759,579) in view of Sakamoto et al. (US Patent 4,828,840) have been considered but are moot in view of the new ground(s) of rejection. However, because the teachings of Shah et al. and Singh et al. are used in the instant rejection, the Examiner has addressed Applicant's arguments below.

Applicant argues that Singh fails to disclose controlled release coated particles and that Shah et al. fails to disclose the coating of particles with an enteric polymer. However, the Examiner disagrees with Applicant's arguments because Singh et al. teach a pharmaceutically acceptable liquid suspension system provided for solid finely divided pharmaceutical actives such as antihistamines, decongestants, antitussives,

expectorants, non-steroidal anti-inflammatory drugs (NSAIDs) and other analgesic drugs such as acetaminophen and phenacetin(column 2, lines 30-43), ibuprofen, naproxen, and ketoprofen (column 3, lines 12-15). Shah et al. teach a dosage form comprising an extended releasing portion (abstract). The extended release portion comprises coated core particles where the coating comprises an enteric polymer (col. 5, lines15-20; examples). Shah et al. teach that the formulation can be dispersed in water in order to form a suspension (col. 4, lines 15-17). The teaching of Sakamoto et al. was joined to show that the uses of a controlled release formulation comprising a coated dosage form wherein the coating comprises a combination of water-insoluble polymers and enteric polymers (abstract) was known at the time the instant application was filed . Thus, all the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention. It is noted by the Examiner that Applicant is arguing against the cited references individually. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller,* 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Conclusion

The claims remain rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Courtney A. Brown whose telephone number is 571-270-3284. The examiner can normally be reached on 9:00 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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